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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/856,927      | 09/19/2001  | Michael Dean         | 015280-382100US     | 6490             |

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EXAMINER

HUFF, SHEELA JITENDRA

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 08/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/856,927

Applicant(s)

DEAN ET AL.

Examiner

Sheela J Huff

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 3-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election of Group I, claims 1-2 in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

***Priority***

After a careful review of the provisional application, it is determined that applicant has priority to 11/30/98, which is the filing date of the provisional application.

***Information Disclosure Statement***

The IDS filed 7/15/03 has been considered and an initialed copy of the PTO-1449 is enclosed.

***Claim Rejections - 35 USC § 112***

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a genus claim which encompasses any protein which confers mitoxantrone resistance to S1-M1-80 humans colon carcinoma cells and binds to

polyclonal antibodies with bind to SEQ ID No. 2 or 4 and has a MW between 70-75 kDa. While SEQ ID No. 2 and 4 are adequately described in the specification, applicant has not sufficiently described the protein that would bind to antibodies that bind to SEQ ID No. 2 or 4. The specification and claim do not indicate what distinguishing attributes are shared by the member of the genus. Structural features that could distinguish compounds in the genus from other in the protein class are missing from the disclosure. No common structural attributes identify the members of the genus. The specification provides no examples of such protein nor does the specification show the use of a screening assay used to determine mitoxantrone resistance. The general knowledge and the level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to described the common attributes or characteristics that identify the member of the genus SEQ ID No. 2 or 4 alone are insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent,

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except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Doyle, Proceeding of the American Association for Cancer Research 39:657 (3/98) (reference AE on IDS filed 7/15/03 as evidence by Doyle et al PNAS USA 95:15665 (12/98) (reference AJ on IDS filed 7/15/03).

This abstract discloses a Breast Cancer Resistance Protein, which as a novel ATP-binding cassette (ABC) transporter. The protein is approximately 663 amino acids in length and as evidenced by the PNAS paper and the attached sequence alignments. The sequences in the PNAS paper and those of the instant invention have either 99.8% identity (SEQ ID No. 2) or 81% identity (SEQ ID No. 4). It is the Examiner's position that the protein in the 1996 abstract and that in the PNAS paper are the same, especially in view of the fact that the abstract in the PNAS paper is the same as that of the 1996 abstract.

It is the Examiner's position that the 663 amino acid protein has a molecular weight of about 73 kDa (this is based on assuming that the average MW of an amino acid is 110 Da and multiplying 110 by 663). It is inherent that the protein can confer mitoxantrone resistance to S1-M1-80 human colon carcinoma cells. The protein in the reference will bind to polyclonal antibodies that bind SEQ ID No. 2 or 4 because the protein in the paper is either 81% or 99% identical to said sequences.

Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Doyle, Proceeding of the American Association for Cancer Research 39:657 (3/98)

(reference AE on IDS filed 7/15/03 as evidence by Doyle et al PNAS USA 95:15665 (12/98) (reference AJ on IDS filed 7/15/03).

This abstract discloses a Breast Cancer Resistance Protein, which as a novel ATP-binding cassette (ABC) transporter. The protein is approximately 663 amino acids in length and as evidenced by the PNAS paper and the attached sequence alignments, the sequences in the PNAS paper and those of the instant invention have either 99.8% identity (SEQ ID No. 2). It is the Examiner's position that the protein in the 1996 abstract and that in the PNAS paper are the same, especially in view of the fact that the abstract in the PNAS paper is the same as that of the 1996 abstract.

It is the Examiner's position that the 663 amino acid protein has a molecular weight of about 73 kDa (this is based on assuming that the average MW of an amino acid is 110 Da and multiplying 110 by 663). It is inherent that the protein can confer mitoxantrone resistance to S1-M1-80 human colon carcinoma cells. The protein in the reference will bind to polyclonal antibodies that bind SEQ ID No. 2 because the protein in the paper is 99% identical to said sequence.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Ross et al US 6313277 (which has priority to 60/073763, filed 2/5/98)

This reference discloses a Breast Cancer Resistance Protein (SEQ ID No. 1), which as a novel ATP-binding cassette (ABC) transporter. As evidence by the sequence alignments (see attached), SEQ ID NO. 1 of the reference has 81% identity to SEQ ID No. 4 and 99.4% identity to SEQ ID No. 2.

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It is the Examiner's position that the 663 amino acid protein has a molecular weight of about 73 kDa (this is based on assuming that the average MW of an amino acid is 110 Da and multiplying 110 by 663). It is inherent that the protein can confer mitoxantrone resistance to S1-M1-80 human colon carcinoma cells. The protein in the reference will bind to polyclonal antibodies that bind SEQ ID No. 2 or 4 because the protein in the paper is either 81% or 99% identical to said sequences.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by Ross et al US 6313277 (which has priority to 60/073763, filed 2/5/98)

This reference discloses a Breast Cancer Resistance Protein (SEQ ID No. 1), which as a novel ATP-binding cassette (ABC) transporter. As evidence by the sequence alignments (see attached), SEQ ID NO. 1 of the reference has 99.4% identity to SEQ ID No. 2.

It is the Examiner's position that the 663 amino acid protein has a molecular weight of about 73 kDa (this is based on assuming that the average MW of an amino acid is 110 Da and multiplying 110 by 663). It is inherent that the protein can confer mitoxantrone resistance to S1-M1-80 human colon carcinoma cells. The protein in the reference will bind to polyclonal antibodies that bind SEQ ID No. 2 because the protein in the paper is 99% identical to said sequence.


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**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J Huff whose telephone number is 703-305-7866. The examiner can normally be reached on Tuesday 5:30am-11:30am and Fridays 6:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

  
Sheela J Huff  
Primary Examiner  
Art Unit 1642

sjh